Fact sheet of the interlaboratory comparison:

Virucidal activity PT – 2024 2025

1. Context and objectives:

In 2024 - 2025, the CT2M organizes an international inter-laboratory comparison on tests to evaluate virucidal activity according to standards:

- **EN 16777:2018 -** Chemical disinfectants and antiseptics - Quantitative non-porous surface test without mechanical action for the evaluation of virucidal activity of chemical disinfectants used in the medical area - Test method and requirements (phase 2/step 2)
- **EN 17111:2018** - Chemical disinfectants and antiseptics - Quantitative carrier test for the evaluation of virucidal activity for instruments used in the medical area - Test method and requirements (phase 2, step 2)

The objectives of this proficiency testing are:

- Evaluate the performance of the participants to achieve test according to EN16777 and EN17111
- Identify problems in the participating laboratories that may relate to, for example, their operating procedures, the effectiveness of staff training and supervision, inadequate calibration of equipment,
- Improve client confidence of participants,
- Identify differences between participants,
- Evaluate the performance characteristics of the EN1677 and EN17111 sandards.

2. Proficiency testing item:

EN 16777:

- The product to be tested is a commercial solution of 70% isopropanol.
- The strain tested will be: Norovirus

EN 17111:

- The product to be tested is a commercial solution of 50% glutaraldehyde.
- The strain tested will be: Adenovirus

3. Testing Method:

The technical requirements of the test standards EN 16777 and EN 17111 must be complied with.

A detailed protocol will be provided to each participant at the beginning of the campaign. The test conditions (contact time, temperature, cleanliness/dirt conditions, etc.) will be specified in this detailed protocol.

The comparison will take place in 2 steps:

- Step 1: determination of the effective concentration,
- Step 2: Determination of the reduction rates for 3 imposed concentrations of the product.

4. Conditions for participation

The following conditions must be met in order to take part:

- ✓ Possess the resources and facilities needed to carry out the tests

5. Organization of the proficiency testing:

To guarantee the quality of this campaign, the products to be tested will be provided by the CT2M (for participants located in the European Union) and sent by carrier. The vials will be sent to the postal address indicated in the completed registration form.

Participants located outside the European Union will have to obtain the defined product by their own means. For this, they will be provided with the name of the supplier and the product reference. At the end of each stage, participants will send their results by email by completing the file provided by the CT2M.

6. Assigned values and evaluation of performance:

The assigned value will be established from the robust average of the participants' results, determined from algorithm A defined in ISO 13528. The standard deviation of the aptitude assessment as well as the uncertainties associated with the assigned values will be determined in order to establish the performance scores of each participant.

The objective of this inter-laboratory comparison is to assess the ability of each participant to obtain results in line with the results of all participants:

- Determination of the Z-score or Z' score (depending on the number of participants) for each of the step

The rounding rules and acceptance criteria for performance scores are those described in the ISO 13528 and ISO 17043 standards.

7. Report(s):

The final report will be distributed to all participants. The final report sent by the CT2M must not be distributed by participants outside their organisation. The information contained in the report may not be used by participants for scientific publications or any other communication medium.

8. Provisional schedule:

Key steps	Estimated deadline
End of registrations	07/11/2024
Sending samples, detailed protocol and results file	18/11/2024
Deadline for submission of results (stage 1)	25/01/2025
Deadline for submission of results (step 2)	28/03/2025
Publication of the final report	29/04/2025

9. Price

Participation fees: 750 € net total for one standard / 820 € net total for the 2 standards

This price includes:

- the supply and transport costs of the products under test (only for participant located in the European Union)
- the provision of the results file to be completed, the participation protocol and the final report containing the exploitation of the results and the evaluation of performance.

Option: 150 € net total (in addition to the participation fees)

In addition to the final report, you have the option of receiving a personalised individual report that includes your performance evaluation only.

10. Reciprocal commitments:

CT2M commitments:

The CT2M undertakes to:

- guarantee the confidentiality of participants results and respect their anonymity (*),
- carrying out the performance evaluation in complete impartiality,
- organize and process the results in accordance with the reference applicable documents (ISO 17043, ISO 13528).

(*) The data obtained and generated during the inter-laboratory comparison may be consulted during internal or external audits. Auditors are systematically subject to a confidentiality agreement. For communication purposes (conferences, articles, etc.), the results may be used but in a totally anonymous manner.

Participant commitments:

The participants in this inter-laboratory comparison undertake to:

- respect the protocol provided for carrying out the tests
- provide their results within the deadlines defined by the organizer,
- not to communicate with any other participant who may be known in order to avoid any risk of collusion,
- transmit all the necessary information of the successful completion of the inter-laboratory comparison to all the persons concerned within their laboratory,
- inform the CT2M of any malfunction.

11. Registration and contact:

To take part in the inter-laboratory comparison “Virucidal Activity 2024 - 2025”, please complete the registration form “CT2M: REGISTRATION FORM - ILC Virucidal Activity 2024 - 2025” by clicking on the following link: **https://forms.office.com/e/xihTnRG9Wq** or by scanning the QR Code below:

For further information, please contact us:

- ✓ Email: cilvirucidie@ct2m.fr
- ✓ Phone: +33 (0)4 90 50 90 14

Appendix: Terms of sale

1. Invoicing

Invoicing is carried out after sending the final report or an intermediate report of the proficiency testing. **The settlement is 30 days end of month of the invoice date.**

Every registration fee is due when the campaign is started and won't be cancelled or refund.

2. Loss, degradation or elimination of the test item

In case of loss, damage or elimination of the proficiency test item by a participant, the CT2M reserves the right to claim its amount or purchase and new shipment.

The CT2M cannot be held responsible for loss, disposal or non-receipt of the proficency test item.

3. Number of participants

If number of participants is insufficient for an appropriate statistical treatment, the CT2M reserves the right to cancel this inter-laboratory comparison.

4. Management and storage of personnal data

The CT2M will use the data of the participants in order to communicate with the participant during the the ILC. These datas are also used to send them intermediate and/or final reports. The data may be used for commercial purposes: communication of new features on the website, communication on new ILC or on ILC in which a participant have already participated. The data will be kept for 5 years after the last communication. (The data listed in the quotes and reports are kept for 10 years.)

The provisions governing the management of personal data under the RGPD are available on our website in the "RGPD Policy" document: https://ct2m.fr/presentation-ct2m/politique-rgpd/

In the event of refusal, an email should be sent to ct2m@ct2m.fr.